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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/334,163 06/16/99 NAGEL

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023557 HM22/0130
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EXAMINER

KIMBALL, M

ART UNIT

PAPER NUMBER

1638
DATE MAILED:

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01/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/334,163

Applicant(s)
Nagel

Examiner
Melissa Kimball

Group Art Unit
1638



☒ Responsive to communication(s) filed on Nov 15, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-17 is/are pending in the application

Of the above, claim(s) 13-15 and 17 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-12 and 16 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 445

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

This application should be examined for errors. For example, “and” should appear before the last step of the method of claim 16.

Election/Restriction

1. Applicant's election without traverse of Group I. in Paper No. 7 is acknowledged.

Claim Rejections - 35 USC § 112

2. Claims 1-12 and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ the novel corn seed designated ‘LS1498’, ‘LS0417’ and ‘LS288’. Since the corn seed is essential to the claimed invention it must be either known and readily available to the public or can be made or isolated without undue experimentation. If the corn seed is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the plant. The specification does not disclose a repeatable process to obtain the exact corn seed designated ‘LS1498’, ‘LS0417’ and ‘LS288’ and it is not apparent if the seed is known and readily available to the public. Thus, a perfected deposit may be used for enablement purposes. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. If the deposit is made under the terms of the Budapest Treaty, then an

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affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

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For each deposit made pursuant to these regulations, the specification shall be amended to contain (see M.P.E.P. § 1.809):

- (1) The accession number for the deposit;
- (2) The date of the deposit;
- (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and,
- (4) The name and address of the depository.

3. Claims 1-3, 6-9, 12 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for plants with low mean saturates which originated from mutation breeding of 'Holeisyn', does not reasonably provide enablement for any corn plant with low mean saturate content derived from any method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The instant fact pattern is similar to that in *In re Hyatt*, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983), wherein a single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification at most disclosed only those means known to the inventors. When claims depend on a recited property, a fact situation comparable to *Hyatt* is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification

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discloses at most only those known to the inventor. See also *Fiers v. Sugano*, 984 F.2d 164, 25 USPQ2d 1601 (Fed. Cir. 1993), and MPEP § 2164.08(a).

The specification discloses three corn lines, 'LS1498', 'LS0417' and 'LS288', which were made through mutation breeding of the high oleic line 'Holeisyn'. The specification teaches that the total saturates present in the seed oil of the sublines produced from the three exemplified lines was always lower than that of an elite line, but does not provide evidence of reduced levels of saturates in the seed of mutants derived from any other corn plant. The specification discloses that these plants had low relative levels of saturated fats due to a high levels of oleic acid. The seed did not comprise high levels of the other major monounsaturated fatty acid, linoleic acid. Similarly, reduced saturated fatty acids present in the mutant plants were due to a reduction in palmitic acid while maintaining average levels of stearic acid. However, corn seed with reduced saturates relative to total fatty acids could have very different fatty acid profiles than those of 'LS1498', 'LS0417' and 'LS288' and still be encompassed by the broad claims. The levels of other saturated fatty acids present in the corn seed oil are not disclosed. The claims fail to recite any limitations with regard to what gene(s) are modified or introduced in a corn plant to produce the claimed effect, and thus the skilled artisan would have to resort to trial and error experimentation to identify other mutant plants or transgenic plants meeting the functional limitations of the claims. At the time of the invention, the state of the art established that parental genotype was critical in selection of desired fatty acid profiles in corn by conventional breeding (Pamin et al., page 281, col.2). Pamin et al. teach that selection for high levels of one fatty acid

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may or may not effect the amount of a another one based on the different pathways involved and the different interacions of the specific fatty acids under consideration.

Given the lack of guidance presented in the specification regarding parental selection and the heritability of the various fatty acids influencing the total fatty acid content in corn seed oil, the absence of working examples directed to any other parent plants, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of genotype to fatty acid selection pressures, and the breadth of the claims which fail to recite any limitations to the particular parent or to the specific fatty acid profile responsible for the claimed relative amounts, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

4. Claims 4-5 and 10-11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-5 and 10-11 are vague and indefinite in the recitation of cultivar names absent any deposit accession number.

The designations of cultivar names such as "LS1498" are arbitrary and create ambiguity in the claims. For example, the plant disclosed in this application could be designated by some other arbitrary name or the assignment of the name "LS1498" could be arbitrarily changed to designate another seed or plant. If either event occurs, one's ability to determine the metes and bounds of

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the claim would be impaired. See *In re Hammack*, 427 F.2d 1378, 1382, 166 USPQ 204, 208 (CCPA 1970).

Amending the claims so as to refer to both the ATCC deposit accession number as well as the cultivar names would correct this deficiency. In the interest of compact prosecution, Applicants may refrain from amending the claims until the time of the actual deposit as set forth in 37 CFR 1.801-1.809. Failure to amend claim 4-5 and 10-11, however, will result in abandonment for failure to prosecute.

5. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of “assemblage of corn seeds”. The claims recite specific phenotypic traits for the seeds so one would assume that they are a uniform group of seeds of the same cultivar. However, the claim does not distinctly state that the seeds are of the same cultivar. One could envision a group of seeds that are genetically dissimilar that have only low amounts of saturated fatty acids in common which satisfy the claim limitations. As such, a skilled artisan would be unable to determine the metes and bounds of the claims.

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6. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is indefinite in the limitation "commercially acceptable". No standard is provided in the disclosure and corn plants are bred for various regions and final products. What is acceptable in one region or industry may not be acceptable in another, particularly in the absence of a particular definition of this subjective language.

No claim is allowed.

GENERAL INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Kimball whose telephone number is (703) 305-6999. The examiner can normally be reached on weekdays from 8:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310.

The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MLK

January 25, 2001


GARY BENZION
PRIMARY EXAMINER